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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,472	03/26/2001	Wilson Smart	Kum11Si1.Prb	6422

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GREGORY SMITH & ASSOCIATES
3900 NEWPARK MALL ROAD, 3RD FLOOR
NEWARK, CA 94560

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/816,472

Applicant(s)

Smart et al

Examiner

Robert Nasser

Art Unit

3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above, claim(s) 28-30 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 31, 34, 36, and 37 is/are rejected.
- 7) ☒ Claim(s) 32, 33, and 35 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

Art Unit: 3736

Before beginning, the examiner notes that two references on the IDS were not considered because no copy was included and the information on the IDS does not match the information on that patent number.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, drawn to figure 1.

Species II, drawn to figure 2.

Species III, drawn to figure 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 3736

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. James Leary on September 19, 2002 a provisional election was made with traverse to prosecute the invention of species I, claims 1-28 and 31-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-30 and 38-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claims 4, 6, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is rejected in that it is unclear how a non-uniform taper establishes a continuous change. Claim 6 is rejected in that there is a number missing before

Art Unit: 3736

the word mm in line 2. Claim 25 is rejected in that there is no antecedent basis for the signal carrier.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-15, 26-28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al. Say et al shows a device having a silicone dioxide substrate with a body 50 portion and a microprobe portion 67, where the microprobe portion has a taper (see figure 12), which is a chisel shaped point. The taper is uniform on the portion that tapers, but is non-uniform with respect to the entire microprobe portion. The device further has a sensor located away from the body at the tip of the microprobe, so that it is inserted in the patient's body when in use. The sensor is an electrochemical sensor. The device further has electrical contacts 49 allowing connection to an analyte monitor and electrical conductors running between the sensor and the contacts. With respect to claims 5-8, Say shows the claimed sizes.

“ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

Claims 10, 18-24, 34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al in view of the Kim et al article entitled "Needle-Shaped Glucose Sensor with Multi-Cell Electrode Fabricated by Surface Micro machining." Claim 10 is rejected in that Kim et al shows a needle converging to a point. From this teaching, it would have been obvious to modify Say et al as it is merely the substitution of one known sensor configuration for another. Claims 18-24 are rejected in that Kim et al shows an alternate substrate which is single crystal silicon, which a silicon oxide insulative layer, and then with the electronics being deposited onto the SiO layer. From this teaching, it would have been obvious to modify Say to use such a substrate, as it is merely the substitution of one known equivalent substrate for another. With respect to claims 21-24, the examiner notes that these are merely conventional techniques for forming electrical conductors and contacts onto a semiconductor. With respect to claims 34 and 36, Kim shows multiple sensors for measuring glucose to increase accuracy of measurement. Hence, it would have been obvious to modify Say et al to include multiple sensor, to increase the accuracy.

Claims 11, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al. With respect to claim 11, the exact shaped of the device would have been obvious to one skilled in the art. With respect to claim 25, the examiner takes official notice that optical and electrochemical analyte sensors are interchangeable.

Art Unit: 3736

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al in view of Meade et al. Meade teaches that eletcrogravometric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify Say to use an electrogravometric sensor, as it is merely the substitution of one known equivalent for another.

Claims 32, 33, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kawanaka, Daddonna et al, and Palti all show sensors on substrates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg, can be reached on (703) 308-3130. The fax phone number for this Group is (703) 308-0758.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [max.hindenburg@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

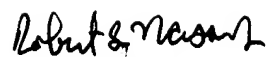
Application/Control Number: 09/816472

Page 7

Art Unit: 3736

RLN

September 21, 2002



ROBERT L. NASSER
PRIMARY EXAMINER